NDA 19-011/S-012, S-013

Braintree Laboratories, Inc.
Attention: Vivian Caballero
60 Columbian Street
P.O. Box 850929
Braintree, MA 02 185-0929

OCT 7 1999

Dear Ms. Caballero:

We acknowledge the receipt of your May 12, 1999 submission containing final printed labeling in response to our letter approving your supplemental new drug application for PINEAPPLE FLAVOR GoLYTELY (PEG-3350 and electrolytes) for Oral Solution.

In the course of our review, we found that you had included a revision to the CONTRAINDICATIONS section of the package insert. This revision was made in response to our letter dated February 26, 1999. For administrative purposes, this labeling change has been designated Supplement —013, with a submission date of May 12, 1999 and a receipt date of May 13, 1999.

Supplement —013 proposes the following change: the addition of a sentence to the **CONTRAINDICATIONS** section of the package insert: "GoLYTELY is contraindicated in patients known to be hypersensitive to any of the components."

We have reviewed the labeling that you submitted in accordance with our March *25*, 1999 letter, and we find it acceptable for Supplement —012.

We have completed the review of Supplement —013 and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use.as recommended in the submitted final printed labeling. Accordingly, this supplemental application is approved effective on the date of this letter.

Please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland *20857*

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3l4.80 and 314.81.

If you have any questions, contact Alice Kacuba, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research